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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/657,118	09/09/2003	Hiroyuki Yokoi	242232US0CONT	9226

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EXAMINER	
GABEL, GAILENE	
ART UNIT	**PAPER NUMBER**
1641	

SHORTENED STATUTORY PERIOD OF RESPONSE	NOTIFICATION DATE	DELIVERY MODE
3 MONTHS	02/23/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Notice of this Office communication was sent electronically on the above-indicated "Notification Date" and has a shortened statutory period for reply of 3 MONTHS from 02/23/2007.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/657,118	YOKOI, HIROYUKI	
	Examiner	Art Unit	
	Gailene R. Gabel	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 November 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4,5 and 7-15* is/are pending in the application.

4a) Of the above claim(s) *12-14* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4,5,7-11 and 15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1,2,4,5 and 7-15* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *9/8/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Amendment Entry

1. Applicant's amendment and response filed on November 24, 2006, is acknowledged and has been entered. Claims 1, 4, 7-9, 11 and 15 have been amended. Claims 3, 6 and 16 have been cancelled. Claims 12-14 remain, withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being claims drawn to a non-elected invention. Accordingly, claims 1, 2, 4, 5 and 7-15 are pending. Claims 1, 2, 4, 5, 7-11, and 15 are under examination.

Withdrawn Rejections

2. All rejections not reiterated herein, have been withdrawn.

3. The rejections of claims 3, 6 and 16 are now moot in light of Applicant's cancellation of the claims.

4. In light of Applicant's amendment and argument, the rejection of claims 1, 2, 4, 5, and 7-11 under 35 U.S.C. 102(e) as being anticipated by Hoshino et al. (US Patent 6,143,510), is hereby, withdrawn.

5. In light of Applicant's amendment and argument, the rejection of claims 1, 2, 4, 5, and 7-11 under 35 U.S.C. 102(b) as being anticipated by Watkins et al. (US Patent 6,280,618), is hereby, withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1, 2, 4, 5, 7-11 and 15 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite and lacks antecedent basis in reciting "the reaction system is comprised of detergent in a concentration range of 0.5 to 5%" because no addition of detergent appears to have been effected in the step of forming the reaction system, or in any of the proceeding method steps in the claim. Accordingly, it is unclear how the detergent is part of the claimed method.

Regarding claim 2, the phrase "type [detergents]" renders the claim indefinite because the claim includes elements not actually disclosed (those encompassed by "detergent types"), thereby rendering the scope of the claim unascertainable. See MPEP § 2173.05(d).

Claim 15 is vague and indefinite. Same analogous comments and problems in claim 2 apply to claim 15.

Claim 15 is indefinite in failing to recite a positive limitation in the claim in reciting, "detergent ... adjusted so that the detergent concentration is 0.5 to 5% when the solution is added to the whole blood sample." Specifically, claim 15 fails to specifically define how the detergent concentration is adjusted, i.e. modified, so as to provide a detergent concentration of 0.5 to 5% in the sample mixture.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1, 2, 4, 5, 7-11 and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Ullman et al. (US Patent 6,103,537).

Ullman et al. disclose an electroseparation binding assay method and kit for quantitative measurement of analyte in a whole blood sample (see Abstract). Specifically, Ullman et al. specifically disclose combining the whole blood sample suspected of containing analyte with antibody (first specific binding partner) immobilized into a synthetic particle that specifically binds the analyte in the whole blood sample, and a labeled antibody (second specific binding partner) that also specifically binds the analyte in the whole blood sample. The mixture is incubated for a time period to allow binding interaction between the antibodies and the analyte so as to form synthetic particle antibody – analyte – labeled antibody complexes (see column 3, lines 20-38, column 4, lines 52-63, column 5, lines 48-57, and column 5, line 66 to column 6, line 5). As summarized in columns 3 and 4, addition of elements in the assay to form a mixture comprising antibody-antigen complexes, may be effected in any selected order, prior to detection. The analyte can be any one of proteins, hormones, and cancer antigens (see

column 6, line 6 to column 8, line 26). The synthetic particles used may be any one of dextran latex , polystyrene, or magnetic particles (see column 13, lines 28-67 and column 18, lines 23-59). Detection of the complexes is performed using different signal producing systems including fluorescent, enzyme, and chemiluminscent labels (see column 11, lines 12-40). Ullman et al. also teach adding surfactants or detergents, binding enhancers, or agents that block non-specific binding in the assay medium including proteins or detergents such as polyalkylene glycols, polyoxyethylene sorbitan monolaureate (Tween 20) and Triton X-100. The concentration of the detergent is about 0.01 to 1% by weight (see column 12, lines 21-29, column 14, lines 46-54, and column 18, lines 63-66). This concentration is within the concentration range of 0.5 to 5%, as claimed.

Since detergents such as polyalkylene glycols, polyoxyethylene sorbitan monolaureate (Tween 20) and Triton X-100 in concentrations of 0.01 to 1% as taught by Ullman et al. do not result to hemolysis, i.e. hemolysis is prevented, it is deemed that Ullman anticipates the claimed invention.

As for the recitation of "the ratio of the whole blood sample and the whole blood treatment solution is in the range of 99:1 to 5:95" in claim 7, it is noted that "1% by weight of the detergent in relation to the total mixture having 99% whole blood" as taught by Ullman, appears to inherently provide a ratio in the range of 99:1, as claimed. Accordingly, it is maintained that Ullmann in as far as this limitation is concerned, inherently anticipates the claimed invention.

Response to Arguments

8. Applicant's arguments filed November 24, 2006 have been fully considered but they are not persuasive.

A) Applicant argues that Ullman et al. does not anticipate the claimed invention because although Ullman et al. disclose adding detergents, they do not disclose the concentration of the detergents or the hemolysis-prevention effect of the detergents. Applicant specifically contends that the concentration of the detergent which is about 0.1 to 1% by weight in column 14, lines 46-54 is not the concentration of a detergent, but rather the concentration of "non-specific protein material such as BSA and BGG.

Contrary to Applicants argument, the referenced citations in all of column 12, lines 21-29, column 14, lines 46-54, and column 18, lines 63-66 in the Ullman reference, are relied upon for their all-encompassing disclosure or teaching of "proteins ... such as albumins (BSA) or BGG, or surfactants, particularly non-ionic surfactants/detergents such as polyalkylene glycols (Tween 20 or TRITON X-100)" as ancillary materials, or treatment reagents to prevent nonspecific binding. The concentration of such material used to prevent non-specific binding is about 0.01 to 1% by weight, . Ullman's teaching of such ancillary materials, use and concentration requirements thereof, appear to be all inclusive, and cannot be construed to be limiting to specific citations within the document, so as to be individually interpreted in a vacuum, as in Applicant's contention. Accordingly, the rejection of claims 1, 2, 4, 5, 7-11, and 15 as being anticipated by Ullman et al. is maintained.

9. For reasons aforementioned, no claims are allowed.

Drawings

10. Prior art made of record are not relied upon but considered pertinent to the applicants' disclosure:

Fridlender et al. (US Patent 4,313,927) disclose immunoassay methods using surfactants/detergents such as polyalkylene glycols (Tween 20) in concentrations of 0.05% as ancillary materials in assay buffer solutions.

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gailene R. Gabel whose telephone number is (571) 272-0820. The examiner can normally be reached on Monday, Tuesday, and Thursday, 7:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Gailene R. Gabel
Patent Examiner
Art Unit 1641
February 19, 2007